Quick Summary for the
Transmissible Spongiform Encephalopathies Advisory Committee

(TSEAC)

Oct 14, 2004

This quick summary provides an unofficial overview of the October 14, 2004 TSEAC meeting until transcripts are available.

The Committee received updates on the following five topics:

#1: USDA BSE Licensed Tests and Enhanced Surveillance Program by Lawrence Elsken, DVM, USDA

#2: USDA Review of Worldwide BSE Situation and USDA Responses by Lisa Ferguson, DVM, USDA

#3: Update on Animal Feed Rulemaking by Burt Pritchett, DVM, CVM, FDA

#4: Labeling Claims for TSE Clearance Studies for Plasma Derivative Products by Dorothy Scott, MD, OBRR, FDA

5: Industry-Wide Data on TSE Clearance from Plasma Products by Henry Baron, MD, Senior Director- Prion Research, ZLB Behring (Speaking on behalf of the Plasma Protein Therapeutics Association)

During the day there were two open public hearing sessions. In the morning the presentations generally focused on diagnostic testing for TSEs. Presentations were made by: Steve Figard, PhD, Abbott Diagnostics; Alan Rudolf, PhD, MBA, Adlyfe Inc.; Johanna Bergmann, PhD, Altegen Inc.; Quentin Tonelli, PhD, IDEXX Laboratories Inc.; and by Roger Rosedale, Microsens Biotechnologies.

In the afternoon open public hearing Peter L. Page, MD, from the American Red Cross presented their "CJD Lookback Study"; Michael Fitzpatrick, PhD, of America's Blood Centers requested FDA consider an "exit strategy" for CJD deferrals. Other presentations and comments were made by: Robert Rohwer, PhD, VA Hospital Baltimore; Merlyn Sayers, MD, PhD, Carter Blood Care; Jonathan Goldsmith, MD, Immune Deficiency Foundation and David Cavenaugh, Committee of Ten Thousand. Three written submissions to the meeting record were received including a copy of a letter from a woman in the UK to her husband's consultant regarding vCJD and questions from her for this meeting, an e-mail from Terry Singletary and an e-mail from Barbara Sachau.

The major topic of the meeting was a discussion entitled, "Consideration of Current FDA-Recommended Safeguards to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products". In preparation for discussion of this topic the Committee listened to the following presentations:

An introduction and overview of the topic by David Asher, MD, OBRR/FDA

Presumptive Transfusion Transmission of vCJD (UK and EU epidemiology, case reports, surveillance and projections, potential public health implications,

and responses) by Professor Robert G. Will, MD, UK CJD Surveillance Unit.

Comparison of the Transfusion Risk for CJD vs. vCJD by Steven Anderson, PhD, OBE/FDA

Leukoreduction and Its Failure to Remove Most Infectivity from Blood, Luisa Gregori, PhD, VA Medical Center

Changes in Canadian CJD/vCJD Blood Safety Policies by Peter Ganz, PhD, HealthCanada

Current Safeguards for Blood Products Recommended by FDA presented by Dorothy Scott, MD, OBRR/CBER

Possible Effects of Prior CJD-Related Blood Donor Deferrals on Blood Supply by Alan Williams, PhD, OBRR/CBER

In light of the recent information presented at this meeting (presented by speakers listed above) the Committee discussed whether the CJD/vCJD deferral policies currently recommended by FDA to protect the safety of the blood supply remained justified. The Committee also discussed possible enhancements to existing policies and possible additional policies that might reduce the risk further without jeopardizing an adequate supply of life-sustaining and health-sustaining blood products.

The following three questions were presented to the Committee:

1. Are the measures currently recommended by FDA to reduce the risk of transmitting CJD and vCJD by blood and blood products still justified?

Committee members were concerned that it was too early to lessen current restrictions especially because there may be a "second wave" of new vCJD cases. They encouraged additional studies and consideration of new technologies and eventual testing that may lead to a greater reduction of risk while not deferring many donors unnecessarily.

The Committee voted: 14 yes, 0 no, 0 abstained.

2. Do the recent scientific data on vCJD warrant consideration by FDA of any additional potentially risk-reducing measures for blood and blood products?

Individual Committee members requested additional studies to collect more data, including studies such as follow-up of UK patients with abnormal prion protein in appendix. With the clarification by FDA that it will continue its current investigations, studies and risk analyses, the Committee voted: 1 yes, 13 no, 0 abstained.

3. If so, please comment on the additional potentially risk-reducing measures that FDA should consider at this time.

The single "yes" voter requested studies of the histories of vCJD patients in other countries beyond those already done in the U.S. and U.K. to learn if treatment with CJD/vCJD-implicated blood products might be involved. He noted that deferral of persons transfused in BSE countries outside of the UK might merit consideration.

Please refer to the committee transcripts for a detailed account of the meeting.